

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
MICHAEL A. GOLLIN
VENABLE LLP
P.O. BOX 34385
WASHINGTON, DC 20043-9998

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing (day/month/year) 03 JUL 2006		
Applicant's or agent's file reference 58086-229763	FOR FURTHER ACTION See paragraph 2 below	
International application No. PCT/US06/11417	International filing date (day/month/year) 29 March 2006 (29.03.2006)	Priority date (day/month/year) 13 May 2005 (13.05.2005)
International Patent Classification (IPC) or both national classification and IPC IPC: A61K 31/4184(2006.01),31/4166(2006.01);C07D 235/02(2006.01),233/86(2006.01) USPC: 514/387,391;548/301.4,321.1		
Applicant THE REGENTS OF THE UNIVERSITY OF CALIFORNIA		

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Date of completion of this opinion 14 June 2006 (14.06.2006)	Authorized Officer Laura L. Stockton, Ph.D. Telephone No. 571/272-1600
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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US06/11417

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed
☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing
☐ table(s) related to the sequence listing

b. format of material

- ☐ on paper
☐ in electronic form

c. time of filing/furnishing

- ☐ contained in the international application as filed.
☐ filed together with the international application in electronic form.
☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
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International application No.

PCT/US06/11417

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 14,36 and 47-51

because:

☐ the said international application, or the said claim Nos. _____ relate to the following subject matter which does not require an international search (*specify*):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 14,36 and 47-51 are so unclear that no meaningful opinion could be formed (*specify*):

The compounds of Tier 1 and Tier 2, as found in claim 14, are not claimed by structure or nomenclature. In claim 36, the compounds of RD162', RD162'', RD 169 and RD 170 are not claimed by structure or nomenclature. In claim 47, it is not clear what the method is to accomplish. A method for what or to do what? Therefore, claims 14, 36 and 47-51 are unsearchable.

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

☐ no international search report has been established for said claims Nos. _____

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13ter.1(a) or (b).

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US06/11417

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>1-13, 15-35 and 37-46</u>	YES
	Claims <u>NONE</u>	NO
Inventive step (IS)	Claims <u>18 and 19</u>	YES
	Claims <u>1-13, 15-17, 20-35 and 37-46</u>	NO
Industrial applicability (IA)	Claims <u>1-13, 15-35 and 37-46</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1-13, 15-17, 20-35 and 37-46 lack an inventive step under PCT Article 33(3) as being obvious over Claussner et al. (U.S. Pat. 6,087,509).

Applicant claims imidazolidine compounds. Claussner et al. teach imidazolidine compounds which are structurally similar to the instant claimed compounds. See in Claussner et al., for example, columns 1, 6-10, 24 and 25. The difference between the compounds of Claussner et al. and the compounds instantly claimed is that the instant claimed compounds are generically described in Claussner et al. The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., anti-androgenic activity).

One skilled in the art would thus be motivated to prepare products embraced by the prior art to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful in treating tumors. The instant claimed invention would have been suggested and therefore, obvious to one skilled in the art.

Claims 18 and 19 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest the compounds found in these claims.

**WRITTEN OPINION OF THE
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International application No.

PCT/US06/11417

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the questions whether the claims are fully supported by the description, are made:

Claim 11 is objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claim 11 is indefinite for the following reason(s): R3 representing "methylcarbonyl" lacks antecedent basis from claim 1.